

**SOLICITOR**

<b>TO:</b> Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450 <b>U.S. PATENT &amp; TRADEMARK OFFICE</b>	<b>MAY - 4 2009</b> <b>REPORT ON THE</b> <b>FILING OR DETERMINATION OF AN</b> <b>ACTION REGARDING A PATENT OR</b> <b>TRADEMARK</b>
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In compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been  
 filed in the U.S. District Court for the District of Maryland on the following ☒ Patents or ☐ Trademarks:

DOCKET NO. RDB-09-CV-1113	DATE FILED 4/30/09	U.S. DISTRICT COURT FOR THE DISTRICT OF MARYLAND
PLAINTIFF PFIZER INC., ET AL		DEFENDANT LUPIN LTD, ET AL
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 6,147,819		
2 6,001,876		
3 5,563,175		
4		
5		

In the above-entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY	<input type="checkbox"/> Amendment <input type="checkbox"/> Answer <input type="checkbox"/> Cross Bill <input type="checkbox"/> Other Pleading
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above-entitled case, the following decision has been rendered or judgment issued:

DECISION/JUDGMENT
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CLERK Felicia C. Cannon	(BY) DEPUTY CLERK 	DATE 5/1/09
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### **PRAYER FOR RELIEF**

WHEREFORE, Pfizer and Northwestern pray for a judgment in their favor and against Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc., and respectfully request the following relief:

- A. A judgment declaring that Lupin has infringed U.S. Patent No. 6,197,819;
- B. A judgment declaring that Lupin has infringed U.S. Patent No. 6,001,876;
- C. A judgment declaring that Lupin has infringed U.S. Patent. No. 5,563,175.
- D. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Lupin, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling the Lupin Products within the United States, or importing the Lupin Products into the United States, prior to the expiration of the '819, '876 and '175 patents;
- E. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 91-040 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '819, '876 and '175 patents, including any extensions;
- F. If Lupin commercially manufactures, uses, offers to sell, or sells the Lupin Products within the United States, or imports the Lupin Products into the United States, prior to the expiration of any of the '819, '876 and '175 patents, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

- G. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;
- H. Costs and expenses in this action; and
- I. Such other relief as the Court deems just and proper.

/s/ George E. Brown

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# EXHIBIT A

## RELATED CASES

*Pfizer Inc., Warner-Lambert Company LLC, CP. Pharmaceuticals International C.V. and Northwestern University v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd., Civil Action No. 09-cv-00307 (D. Del.)*

*Pfizer Inc., Warner-Lambert Company LLC, CP. Pharmaceuticals International C.V. v. Alphapharm Pty. Ltd. and Mylan Pharmaceuticals Inc., Civil Action No. 09-cv-00308 (D.Del.)*

*Pfizer Inc., Warner-Lambert Company LLC, CP. Pharmaceuticals International C.V. and Northwestern University v. Lupin Ltd. and Lupin Pharmaceuticals, Inc., Civil Action No. 09-cv-00309 (D. Del.)*

*Pfizer Inc., Warner-Lambert Company LLC, CP. Pharmaceuticals International C.V. and Northwestern University v. Sandoz Inc., Civil Action No. 09-cv-00310 (D. Del.)*

*Pfizer Inc., Warner-Lambert Company LLC, CP. Pharmaceuticals International C.V. and Northwestern University v. Actavis Elizabeth LLC and Actavis, Inc., Civil Action No. 09-cv-00311 (D. Del.)*

*Pfizer Inc., Warner-Lambert Company LLC, CP. Pharmaceuticals International C.V. and Northwestern University v. Wockhardt Limited and Wockhardt USA, LLC, Civil Action No. 09-cv-00312 (D. Del.)*

*Pfizer Inc., Warner-Lambert Company LLC, CP. Pharmaceuticals International C.V. and Northwestern University v. Sun Pharma Global Inc., Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries, Inc., Civil Action No. 09-cv-00313 (D. Del.)*

*Pfizer Inc., Warner-Lambert Company LLC, CP. Pharmaceuticals International C.V. and Northwestern University v. Cobalt Laboratories, Inc. and Cobalt Pharmaceuticals, Inc., Civil Action No. 09-cv-00315 (D. Del.)*

## CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleading, motion papers or required by law, subpoenas provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

## I. (a) PLAINTIFFS

Pfizer Inc., Warner-Lambert Company LLC, C.P. Pharmaceuticals International C.V. and Northwestern University

(b) County of Residence of First Listed Plaintiff New York  
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

George E. Brown, Esquire, Kramon & Graham, P.A., One South Street, Suite 2600, Baltimore, MD 21202 (410) 752-6030

## DEFENDANTS

Lupin Ltd. and Lupin Pharmaceuticals, Inc.

County of Residence of First Listed Defendant N/A  
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

## II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

## III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- |                                         | PTF                        | DEF                        |                                                               | PTF                        | DEF                        |
|-----------------------------------------|----------------------------|----------------------------|---------------------------------------------------------------|----------------------------|----------------------------|
| Citizen of This State                   | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State     | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State                | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation                                                | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

## IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>PROPERTY RIGHTS:</b> <input type="checkbox"/> 820 Copyrights <input checked="" type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark	<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes
<b>REAL PROPERTY</b> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<b>CIVIL RIGHTS</b> <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 440 Other Civil Rights	<b>PRISONER PETITIONS</b> <input type="checkbox"/> 510 Motions to Vacate Sentence <b>Habeas Corpus:</b> <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition	<b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act <b>IMMIGRATION</b> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 463 Habeas Corpus - Alien Detainee <input type="checkbox"/> 465 Other Immigration Actions	<b>SOCIAL SECURITY</b> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609

## V. ORIGIN

(Place an "X" in One Box Only)

- ☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

## VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):  
35 U.S.C. Section 271 (e)(2)(A).  
 Brief description of cause:  
Patent infringement.

## VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☐ Yes ☒ No

## VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE

See Attached

DOCKET NUMBER

DATE

SIGNATURE OF ATTORNEY OF RECORD

Apr. 30, 2009

Re R

FOR OFFICE USE ONLY

RECEIPT # \_\_\_\_\_ AMOUNT \_\_\_\_\_ APPLYING IFP \_\_\_\_\_ JUDGE \_\_\_\_\_ MAG. JUDGE \_\_\_\_\_

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MARYLAND

PFIZER INC.  
235 East 42<sup>nd</sup> Street  
New York, New York 10017

WARNER-LAMBERT COMPANY LLC  
235 East 42<sup>nd</sup> Street  
New York, New York 10017

C.P. PHARMACEUTICALS  
INTERNATIONAL C.V.  
235 East 42<sup>nd</sup> Street  
New York, New York 10017

NORTHWESTERN UNIVERSITY  
633 Clark Street  
Evanston, Illinois 60208

Plaintiffs,

v.

LUPIN LTD.  
Laxmi Towers, B Wing  
Bandra Kurla Complex  
Bandra (East)  
Mumbai, Maharashtra 400 051, India

and

LUPIN PHARMACEUTICALS, INC.  
Harborplace Tower  
111 South Calvert Street, Suite 2150  
Baltimore, Maryland 21202

SERVE ON: Resident Agent  
Vinita Gupta  
Harborplace Tower  
111 South Calvert Street, Suite 2150  
Baltimore, Maryland 21202

Defendants.

BY \_\_\_\_\_

CLERK OF COURT  
ALLEN H. ROSE

2009 APR 30 P 3:41

U.S. DISTRICT COURT  
DISTRICT OF MARYLAND

RDB 09CV1113

Civil Action No.:



## **COMPLAINT**

Plaintiffs Pfizer Inc., Warner-Lambert Company LLC, C.P. Pharmaceuticals International C.V. (collectively, "Pfizer"), and Northwestern University ("Northwestern," and together with Pfizer, "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") herein allege:

### **NATURE OF THE ACTION**

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Lupin's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Pfizer's pharmaceutical product Lyrica® prior to the expiration of United States Patent Nos. 6,197,819 ("the '819 patent"), 6,001,876 ("the '876 patent") and 5,563,175 ("the '175 patent") which cover Lyrica® or its use.

### **THE PARTIES**

2. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 235 East 42nd Street, New York, New York.

3. Plaintiff Warner-Lambert Company LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 235 East 42nd Street, New York, New York. Pfizer Inc. is the ultimate parent of Warner-Lambert Company LLC.

4. Plaintiff C.P. Pharmaceuticals International C.V. is a limited partnership organized and existing under the laws of the Netherlands, having a place of business at 235 East 42nd Street, New York, New York. Pfizer Inc. is the ultimate parent of C.P. Pharmaceuticals International C.V.

5. Plaintiff Northwestern University is an Illinois corporation, having its principal place of business at 633 Clark Street, Evanston, Illinois.

6. On information and belief, Lupin Ltd. is a company organized and existing under the laws of India, having a principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India. On information and belief, Lupin Ltd., itself and through its wholly owned subsidiary and agent, Lupin Pharmaceuticals, Inc., is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Maryland and throughout the United States. Lupin Ltd. has previously submitted to jurisdiction in this Court, and has availed itself of the jurisdiction of this Court by asserting counterclaims in lawsuits filed in the United States District Court for the District of Maryland.

7. On information and belief, Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Virginia, having a principal place of business at 111 S. Calvert St., Ste. 2150, Baltimore, Maryland. On information and belief, Lupin Pharmaceuticals, Inc. is an agent and wholly owned subsidiary of Lupin Ltd.

### **JURISDICTION AND VENUE**

8. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Lupin by virtue of, inter alia, its presence in Maryland, having conducted business in Maryland, having availed itself of the rights and benefits of Maryland law, previously consenting to personal jurisdiction in this Court, availing itself of the jurisdiction of this Court, and having engaged in systematic and continuous contacts with the State of Maryland.

10. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

### **THE PATENTS-IN-SUIT**

11. On March 6, 2001, the United States Patent and Trademark Office issued the '819 patent, entitled "Gamma Amino Butyric Acid Analogs and Optical Isomers." At the time of its issue, the '819 patent was assigned to Northwestern, and Northwestern currently holds title to the '819 patent. A copy of the '819 patent is attached hereto as Exhibit A.

12. Northwestern has exclusively licensed the '819 patent to Warner-Lambert Company LLC.

13. On December 14, 1999, the United States Patent and Trademark Office issued the '876 patent, entitled "Isobutyl GABA and Its Derivatives for the Treatment of Pain." At the time of its issue, the '876 patent was assigned to Warner-Lambert Company, which subsequently became Warner-Lambert Company LLC. Warner-

Lambert Company LLC currently holds title to the '876 patent. A copy of the '876 patent is attached hereto as Exhibit B.

14. On October 8, 1996, the United States Patent and Trademark Office issued the '175 patent, entitled "GABA and L-Glutamic Acid Analogs For Antiseizure Treatment." At the time of its issue, the '175 patent was assigned to Northwestern and Warner-Lambert Company. Warner-Lambert Company subsequently became Warner-Lambert Company LLC. Northwestern and Warner-Lambert Company LLC currently hold title to the '175 patent. A copy of the '175 patent is attached hereto as Exhibit C.

15. Northwestern has exclusively licensed the '175 patent to Warner-Lambert Company LLC.

### LYRICA®

16. Pfizer Inc., itself and through its wholly owned subsidiary C.P. Pharmaceuticals International C.V., holds approved New Drug Application Nos. 21-446, 21-723 and 21-724 ("the Lyrica NDAs") for pregabalin capsules in 25, 50, 75, 100, 150, 200, 225 and 300 mg dosage strengths, which are sold by Pfizer under the trade name Lyrica®.

17. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '819, '876 and '175 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Lyrica®.

### **LUPIN'S ANDA**

18. On information and belief, Lupin submitted ANDA No. 91-040 (“the Lupin ANDA”) to the FDA, pursuant to 21 U.S.C. §§ 355(j), seeking approval to market pregabalin capsules in 25, 50, 75, 100, 150, 200, 225 and 300 mg dosage strengths. The pregabalin capsules described in the Lupin ANDA are herein referred to as the “Lupin Products.”

19. The Lupin ANDA refers to and relies upon the Lyrica NDAs and contains data that, according to Lupin, demonstrate the bioequivalence of the Lupin Products and Lyrica®.

20. Pfizer and Northwestern received from Lupin a letter, dated March 23, 2009 (the “Lupin Notification”), stating that Lupin had included a certification in the Lupin ANDA, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the ‘819, ‘876 and ‘175 patents are invalid, or will not be infringed by the commercial manufacture, use, or sale of the Lupin Products (the “Paragraph IV Certification”).

### **COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,197,819**

21. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-20 of this Complaint.

22. Lupin has infringed the ‘819 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Lupin ANDA, by which Lupin seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Lupin Products prior to the expiration of the ‘819 patent.

23. Lupin's commercial manufacture, use, offer to sell, or sale of the Lupin Products within the United States, or importation of the Lupin Products into the United States during the term of the '819 patent would further infringe the '819 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

24. Plaintiffs will be substantially and irreparably harmed if Lupin is not enjoined from infringing the '819 patent.

25. Plaintiffs have no adequate remedy at law.

26. This case is an exceptional one, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

**COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,001,876**

27. Pfizer realleges and incorporates by reference the allegations of paragraphs 1-26 of this Complaint.

28. Lupin has infringed the '876 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Lupin ANDA, by which Lupin seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Lupin Products prior to the expiration of the '876 patent.

29. Lupin's commercial manufacture, use, offer to sell, or sale of the Lupin Products within the United States, or importation of the Lupin Products into the United States during the term of the '876 patent would further infringe the '876 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

30. Pfizer will be substantially and irreparably harmed if Lupin is not enjoined from infringing the '876 patent.

31. Pfizer has no adequate remedy at law.

32. This case is an exceptional one, and Pfizer is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

**COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 5,563,175**

33. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-32 of this Complaint.

34. Lupin has infringed the '175 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Lupin ANDA, by which Lupin seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Lupin Products prior to the expiration of the '175 patent.

35. Lupin's commercial manufacture, use, offer to sell, or sale of the Lupin Products within the United States, or importation of the Lupin Products into the United States during the term of the '175 patent would further infringe the '175 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

36. Plaintiffs will be substantially and irreparably harmed if Lupin is not enjoined from infringing the '175 patent.

37. Plaintiffs have no adequate remedy at law.

38. This case is an exceptional one, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.